K113248
Page 1 of 2

510(k) Summary

as required by 807.92

JAN 17 2012

1. Company Identification

Konica Minolta Medical & Graphic, Inc.
No.1 Sakura-machi, Hino-shi, Tokyo 191-8511, Japan
Establishment Registration Number: 3004485675

2. Submitter's Name and Address

Shigeyuki Kojima
Manager
Regulations and Standards Section, Quality Assurance Center
No. 1 Sakura-machi, Hino-shi, Tokyo 191-8511, Japan
Telephone: 81-42-589-8429
Fax: 81-42-589-8053

3. Date of Submission

December 22, 2011

4. Device Trade Name

AeroDR SYSTEM with P-21

5. Common Name

Digital Radiography

6. Classification, Product Code

Class Ⅱ, 90MQB and 90LLZ

7. Predicate Device

AeroDR SYSTEM, 510(k) number K102349

8. Device Description

The AeroDR SYSTEM, K102349 is a digital imaging system to be used with diagnostic x-ray systems. It consists of AeroDR Detector (flat panel digital detector), Console CS-7 (operator console), AeroDR Interface Unit, AeroDR Generator Interface Unit, AeroDR Access Point and AeroDR Battery Charger. Images captured with the flat panel digital detector can be communicated to the operator console via wired connection or wireless, depend on user's choice.

The modification was made to the AeroDR SYSTEM with P-21 to add the

different panel size. The panel size of 17 x 17 inches (P-21) is added to 17 x 14 inches. The materials of the panel remain unchanged and no other changes were made other than the panel size from 17 x 14 inches to 17 x 17 inches.

9. Indications for Use

The AeroDR SYSTEM with P-21 is indicated for use in generating radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in general-purpose diagnostic procedures. The AeroDR SYSTEM with P-21 is not indicated for use in mammography, fluoroscopy, tomography and angiography applications.

10. Performance Testing

Performance data from non-clinical testing of the AeroDR SYSTEM with P-21 is compared with data from the predicate device, AeroDR SYSTEM (P-11). This comparison showed that the AeroDR SYSTEM with P-21 performed as well as the predicate device.

11. Substantial Equivalence to Predicate Device

The Indications for Use of proposed device and predicate devices are identical. The materials of the panel remain unchanged. The results of performance testing shows that there is no new safety and efficacy issue of the proposed device introducing those already have identified with the predicate device.

The proposed device, AeroDR SYSTEM with P-21 is substantial equivalent to the predicate device, AeroDR SYSTEM.

12. Safety Information

The AeroDR SYSTEM with P-21 has been tested and shown to meet the requirements of IEC 60601-1 and IEC 60601-1-2.

The Risk Analysis for the AeroDR with P-21 was conducted on the basis of ISO14971, "Medical devices – Application of risk management to medical devices". As a result of risk control measures, the risk associated with all of the identified hazards was reduced to an acceptable level.

13. Conclusion

Comprehensively, we judged that the AeroDR SYSTEM with P-21 has the same technological characteristics as the predicate devices. This 510(k) has demonstrated substantial equivalence as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Konica Minolta Medical & Graphic, Inc.
% Mr. Russel Munves
Official Correspondent
Storch, Amini & Munves, P.C.
140 East 45th Street
25th Floor, Two Grand Central Tower
NEW YORK NY 10017

AUG 20 2013

Re: K113248
Trade/Device Name: AeroDR SYSTEM with P-21
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR and MQB
Dated: December 22, 2011
Received: December 23, 2011

Dear Mr. Munves:

This letter corrects our substantially equivalent letter of January 17, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K113248
Page 1 of 1

Indications for Use

510(k) Number (if known) : K113248

Device Name : AeroDR SYSTEM with P-21

Indications for Use:

The AeroDR SYSTEM with P-21 is Indicated for use in generating radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in general-purpose diagnostic procedures.
The AeroDR SYSTEM with P-21 is not indicated for use in mammography, fluoroscopy, tomography and angiography applications.

Prescription Use__X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

Division Sign-off
Office of In Vitro Diagnostic Devices
Evaluation and Safety

510(k) K113248